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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1997

Bausch and Lomb Incorporated
Attention: George M. Burditt, Esq.
Burditt and Radzius, Chartered
333 West Wacker Drive
Suite 2600
Chicago, Illinois 60606-1218

Dear Mr. Burditt:

This is in response to your request for an advisory opinion under 21 CFR 10.85 concerning issues with respect to the labeling of contact lens care products raised in the pending action in the Supreme Court of the State of New York entitled Kramer v. Bausch and Lomb, Inc., Index No. 110972/95. We have considered your request along with the attached Decision of Justice Ira Gammerman issued on May 12, 1997, as well as the papers submitted by both sides in connection with Bausch and Lomb's Motion for Summary Judgement and its subsequent Motion To Renew.

In his decision, Justice Gammerman invoked the primary jurisdiction of the Food and Drug Administration (FDA) regarding the appropriateness of the labeling of the contact lens care products at issue and stayed the action for the purpose of obtaining an opinion from FDA concerning this issue. FDA is granting your request and is issuing the following advisory opinion.

The labeling of each of the contact lens care products at issue[1] was reviewed by FDA as part of a complete premarket approval process under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) ("the Act") . As part of this process, FDA determined that the labeling of each of these products is proper and appropriate in all respects.

We would not permit Bausch and Lomb, or any other contact lens care manufacturer, to disclose in the labeling, packaging or advertising of an in-eye use contact lens care product, such as rewetting drops, that it is chemically identical to or interchangeable with a contact lens care product such as saline, cleaning or conditioning solution. On April 3, 1997, FDA issued an advisory opinion (attached) in response to a request made on behalf of Bausch and Lomb, in which we set forth our policy precluding such disclosure and the underlying health and safety considerations. The substance of that advisory opinion, which remains in effect without modification, is directly relevant to the appropriateness of the labeling of the products here at

[1]Sensitive eyes saline solution; Sensitive Eyes Drops; Sensitive Eyes Saline/Cleaning Solution; Renu Lens Rewetting Drops; Boston Conditioning Solution; Boston Rewetting Drops

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issue. The contention that the labeling of the products should have provided full and accurate disclosure of product identicality and interchangeability, with a warning with respect to possible misuse, is contrary to our policy, and would be contrary to the health and safety of consumers.

As part of the PMA process for each of these products, we reviewed the accuracy of the description of ingredients on the proposed labeling before we cleared the product for marketing. We believe that the description of ingredients of each of these products is accurate and appropriate and in compliance with the Act and applicable regulations in Title 21 of the Code of Federal Regulations (21 CFR). We did not and do not consider slight differences in the description of ingredients of chemically identical products, so long as they are accurate here, to be misleading, inappropriate, or detrimental to consumers. The April 3, 1997 advisory opinion sheds additional light on this issue.

For example, there is nothing false or misleading in a description of Sensitive Eyes Saline Solution as a "sterile, isotomic, buffered solution", whereas Sensitive Eyes Drops which utilizes the same chemical formulation is described as "a sterile, buffered aqueous solution". Both descriptions are correct and appropriate and the slight difference in words is not substantive. This is also true with respect to the description of Sensitive Eyes Saline Solution as "safe and thimerosal free", while Sensitive Eyes Drops is described as "a gentle, thimerosal free, preserved solution". Similarly, there is nothing false or misleading in describing Sensitive Eyes Saline/Cleaning Solution as "a sterile isotomic buffered solution", while describing the chemically identical Renu Lens Wetting Drops as "a sterile, isotomic solution". Both descriptions are accurate and appropriate and were reviewed and cleared by FDA.

We also find that it is appropriate for Bausch and Lomb to recommend that its saline solution be used with its rewetting drops, where both products are compatible in their preservative formulation. Use of such compatible products minimizes the possibility of an adverse or allergic reaction. Specifically, we consider this recommendation to be appropriate in the case of Sensitive Eyes Saline Solution and Sensitive Eyes Drops, because they share the same preservative formulation. For users of Sensitive Eyes Saline Solution who desire to rewet their lenses, Bausch and Lomb could not have recommended that they use Sensitive Eyes Saline Solution as a rewetting drop for the reasons set forth in the April 3, 1997 advisory opinion. Therefore, it is appropriate and neither false nor misleading under the Act and regulations for Bausch and Lomb to recommend in its labeling for Sensitive Eyes Saline Solution that consumers use Sensitive Eyes Drops and *vice versa.*

FDA believes that it would not be appropriate for Bausch and Lomb to reveal that Bausch and Lomb Eye Wash is chemically identical to Sensitive Eyes Saline Solution and Sensitive Eyes Drops: nor does FDA believe that it is inconsistent for Bausch and Lomb to sell Eye Wash in a 4 ounce bottle, while limiting in-eye use contact lens care solutions to bottle sizes

of no more than 30 ml. Eye Wash, which is regulated by FDA as a drug rather than a contact lens care product., is used differently than rewetting drops. The drops are dispensed into the eye several drops at a time, while contact lenses remain in the eye. To permit a large bottle, such as the 4 ounce eye wash, to be used as an eye drop would be dangerous to consumers as stated in our April 3, 1997 advisory opinion. Eye Wash, to the contrary, is used in large quantities, with lenses not in the eye, to flush out the eye. Any promotion of Bausch and Lomb Eye Wash, which would refer to its chemical identicality with sensitive Eyes drops, would be precluded because the latter can only be promoted in a 30 ml or smaller bottle, and labeling which would reveal this identicality or interchangeability would violate the conditions of approval for the marketing of the eye drops. To permit otherwise, a manufacturer would be doing indirectly what it is prohibited from doing directly.

Sincerely,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health